

U.S. Application No. 10/696,464

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### III. REMARKS

Applicants respectfully request reconsideration of this application in view of the following remarks.

#### 1. Status of the Claims

Claims 1-46 are pending in this application. Claims 34-38 and 40-43 have been withdrawn. No claims have been canceled and no new claims have been added in this paper. Accordingly, Claims 1-33, 39 and 44-46 are now pending for examination on the merits.

#### 2. Restriction Requirement

The Examiner has indicated that restriction to one of the following inventions is required under 35 U.S.C. §121:

Group I: Claims 1-33, 39 and 44-46 drawn to compound of formula I wherein  $p=1$  and one of W, X, Y and Z is nitrogen or  $N \rightarrow O$ , a pharmaceutical composition comprising a therapeutically effective amount of a compound of any of Claims 1-33 and a process for preparing a compound of formula I, classified in class 546 and various subclasses;

Group II: Claims 1-17, 20-24, 39 and 44-46 drawn to compound of formula I wherein  $p=1$  and two of W, X, Y and Z are nitrogen or  $N \rightarrow O$ , a pharmaceutical composition comprising a therapeutically effective amount of a compound of any of Claims 1-33 and a process for preparing a compound of formula I, classified in class 544 and various subclasses;

Group III: Claims 1-19, 39 and 44-46 drawn to compound of formula I wherein  $p=2$  and one of W, X, Y and Z is nitrogen or  $N \rightarrow O$ , a pharmaceutical composition comprising a therapeutically effective amount of a compound of any of Claims 1-33 and a process for preparing a compound of formula I, classified in class 546, subclasses 187-193;

Group IV: Claims 1-17, 39 and 44-46 drawn to compound of formula I wherein  $p=2$  and two of W, X, Y and Z are nitrogen or  $N \rightarrow O$ , a pharmaceutical composition comprising a therapeutically effective amount of a compound of any of Claims 1-33 and a process for preparing a compound of formula I, classified in class 544 and various subclasses;

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- Group V: Claim 34 drawn to a compound of formula IV, which is an intermediate of Group II, classified in various classes and subclasses;
- Group VI: Claim 35 drawn to a compound of formula V, which is an intermediate of Group II, classified in various classes and subclasses;
- Group VII: Claim 36 drawn to a compound of formula VI, which is an intermediate of Group III, classified in various classes and subclasses;
- Group VIII: Claim 37 drawn to a compound of formula VII, which is an intermediate of Group IV, classified in various classes and subclasses;
- Group IX: Claim 38 drawn to a compound of formula VIII, which is an intermediate of Group V, classified in various classes and subclasses;
- Group X: Claims 40-43 drawn to a method for treating a mammal having a medical condition alleviated by treatment with a muscarinic receptor antagonist, classified in various classes and subclasses.

In response, Applicants elect Group I with traverse in part. More specifically, Applicants respectfully traverse the requirement for restriction of Groups I-IV for the following reasons.

The basis for the restriction of Groups I-IV is set forth in the Office Action as follows:

The compounds of groups I-IV differ in elements, bonding arrangements and chemical structure to such an extent that a reference anticipating any one group would not render another group obvious, thus unpatentability of any group would not necessarily imply unpatentability of another group. The search for each diverse core structure as delineated is not coextensive with each other and will constitute an enormous burden. Office Action at page 3.

Applicants begin by noting that the Examiner is dividing individual claims into separate restriction groups based on members in Markush groups. In this regard, MPEP §803.02 clearly sets forth that it is improper to require restriction of the members of a Markush group unless the subject matter in the claim lacks unity of invention. Unity of

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invention exists where compounds included within a Markush group (a) share a common utility and (b) share a substantial structural feature essential to that utility.

In the present case, the Examiner has not specifically addressed the question of unity of invention and thus, has not analyzed whether the compounds subject to restriction share a common utility and a substantial structural feature essential to that utility. For this reason alone, the present restriction requirement for Groups I-IV should be withdrawn.

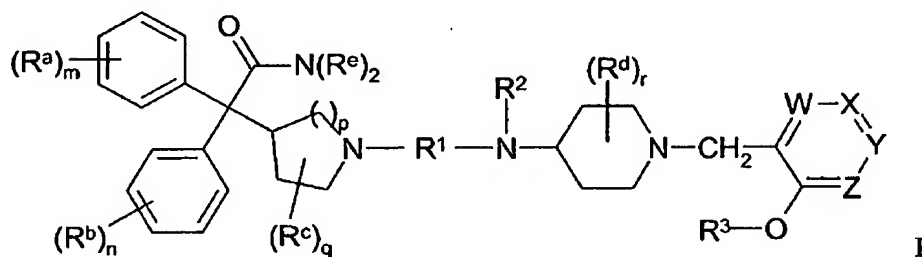
Moreover, upon careful examination, it is clear that the compounds of Groups I-IV share a common utility and a substantial structural feature essential to that utility.

(a) Common Utility

The compounds of Groups I-IV share a common utility; for example, they are all muscarinic receptor antagonists. See, for example, page 51, lines 16-17 of the specification which states "[t]he substituted 4-amino-1-(pyridylmethyl)piperidine and related compounds of this invention are useful as muscarinic receptor antagonists...."

(b) Substantial Structural Feature

The compounds of Groups I-IV share a substantial structural feature essential for their common utility. Specifically, the compounds of these groups share the common structural features found in formula I:



I

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As is readily apparent from this formula, a substantial portion of the compounds in these groups is identical. These common structural features provide the compounds of formula I with their utility as muscarinic receptor antagonists.

The Examiner, however, has chosen to restrict the compounds in these groups based on minor structural differences. For example, the only difference between Group I and Group II is whether the compound of formula I has one or two nitrogen atoms (or an *N*-oxide) at the variables W, X, Y and Z. Additionally, the only difference between the compounds in Group III and Group IV is whether the compound of formula I has a five or six membered ring as defined by the variable "p." Thus, the compounds in Groups I-IV share a substantial structural feature essential to their common utility and differ only in minor structural features.

Accordingly, since the compounds in Groups I-IV share a common utility and a substantial structural feature essential to that utility, they do not lack unity of invention. Therefore, the requirement for restriction is improper and should be withdrawn.

When determining whether the present restriction requirement is proper, it is equally important to consider the fundamental principle that an applicant for a patent has a right to have each claim considered on the merits without the claim being "chopped up" into fragmentary claims by the examiner. This fundamental principle was best expressed in *In re Weber, Soder and Boksay* where the court stated:

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *In re Weber, Soder, and Boksay*, 580, F.2d 455, 458-459, 198 U.S.P.Q. 328, 331-332 (C.C.P.A. 1978) (emphasis in original).

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In the present case, the Examiner is dividing Applicants' claims into fragmentary claims which may never be the equivalent of the original claim and which may have been conceived of only by the Examiner. For example, the Examiner has divided the subject matter of Claim 1 into four separate groups.

In view of the strong admonition by the court that applicants have a right to have each claim examined on the merits and the fact that the Examiner has not demonstrated that the compounds of Groups I-IV lack unity of invention, Applicants respectfully request that the requirement for restriction of Groups I-IV be withdrawn.

3. Election of Species

The Examiner has indicated that an election of species is required. Specifically, the Examiner has indicated that if Group I is elected, an election of species with regard to variables R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, W, X, Y and Z is required.

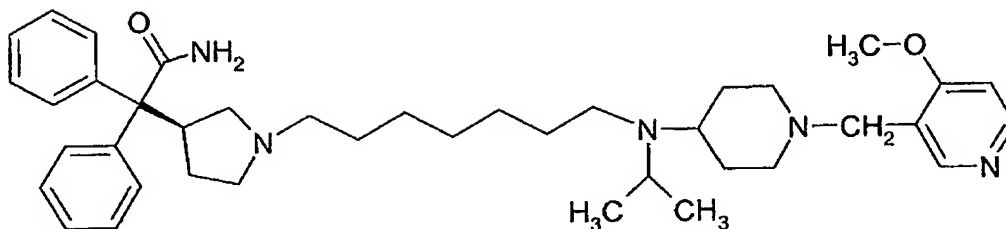
In response, Applicants elect, with traverse, a compound of formula I where the variables are defined as follows:

R <sup>1</sup>	=	-(CH <sub>2</sub> ) <sub>7</sub> -
R <sup>2</sup>	=	isopropyl
R <sup>3</sup>	=	methyl
W	=	CH
X	=	N
Y	=	CH
Z	=	CH

Claims 1-6, 13-15, 18-31, 39 and 44-46 read on or relate to the elected species.

More specifically, Applicants elect the compound of Example 1 (beginning at page 79, line 1), which compound has the following complete structure:

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Claims 1-6, 13-15, 18-31, 39 and 44-46 read on or relate to this elected species.

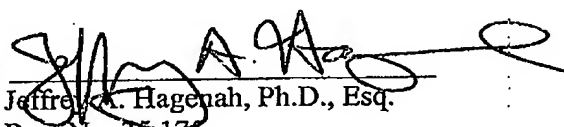
Applicants traverse the election of species requirement on the grounds that a search and examination of the entire genus can be performed without serious burden due to the common structural core and features of the genus.

#### IV. CONCLUSION

Reconsideration of this application in view of the above remarks is respectfully requested. Should there be any questions regarding this paper or this application, or if the Examiner believes any issues can be resolved by telephone, Examiner is encouraged to call the undersigned attorney for Applicants at (650) 808-6406.

Respectfully submitted,  
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